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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|--------------------------|------------------------|
| 10/826,105 | 04/16/2004 | Mark D. Soll | MER 04-024 | 9262 |
| 7590 Judy JARECKI-BLACK, Ph.D., J.D. 3239 Satellite Blvd. Duluth, GA 30096 | | | EXAMINER LEVY, NEIL S | |
| | | | ART UNIT 1615 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/826,105

Applicant(s)

SOLL ET AL.

Examiner

NEIL LEVY

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-29, 33, 37 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-29, 33, 37 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 26-29, 33, 37 and 39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection over solvents commonly used for dermal application, such as transcutal, is withdrawn in view of attorney's pointing to Examples 7-10 for

Support of the premix. Claim 39 as amended is now considered.

Claim Rejections - 35 USC § 112 are withdrawn in consideration of amendments & attorney's arguments.

Claim Rejections - 35 USC § 103

Claims 26-29, 33, 37 & 39 stand rejected under 35 U.S.C. 103(a) as being unpatentable over ALIG et al US006265430B in view of CLEVERLY et al US 2004/0037869 and HUBER 6569886 and FREEHAUF-US 20050136087

The previous rejection, which attorney so eloquently destroyed, inadvertently listed the wrong Alig reference. However, examiner finds the claimed invention to be a premix, the exact active pesticide or pesticides, so long as compatible with each other, the solvent systems, & the balance of the adjuvants & excipients to not be critical to the presentation of the premix.

ALIG shows the instant fipronil derivatives at Table 1 A. Table I provides for haloalkyl at -example 4, at col. 22 as the fipronil substituted thioamide derivative of instant claim 39. Compositions of the instant claimed formulation include components of paraffin, oils, and organic solvents, including glycols, similar to the instant organics of

claim 33 (column 14, lines 33-41), with corn cobs and corn meals (column 14, lines 55) & surfactants (lines 55-59). Glycols shown include ethylene glycol monomethyl ether (top, col. 29).

Additional parasitocides include avermectins (column 1, lines 17,18,35,45) & IGRs (lines 46,58, 66). Oral formulations for cattle, pets and other animals are at column 18, lines 12-16,25-28. Alig does not have all claimed components, as applicant points out.

CLEVERLY also provides fipronil derivatives [0088] and shows fipronil and avermectin [0062, 0065] of the instant formulations inclusive of a 20-60% [0043] corn cob or corn meal [0021] filler, pH modifier, 0.05-1% antioxidant [0049] and surfactant [0054-0060]. Tablet forms include 0.01-20% waxes (claim 53) [0189].

HUBER has fipronil derivatives, fed with ivermectins, & uses solvents in tablets, pills, and dietary supplements and premixes for medicated diets. carriers include waxes.

FREEHAUF has Avermectins as premix[0002,0052]. The instant claimed excipients are shown for a premix at [0016-0023] . These are the ingredients of instant claim 26, & 33 except for the solvent. The instant claim 26 is better shown for the premix components at [0025-0032]. It is not critical as to the specific pesticides one would use, so long as they are orally effective. Avermectin is one of the instantly claimed pesticides, so appropriate to the inclusion of the components as presented in the % presented for Avermectin by FREEHAUF.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize pest control means, to use any of art recognized means, as of the ALIG formulations, modified as desired to permit application in feeds for animals. FREEHAUF details the excipients one would use for oral delivery as a pesticidal medicament as a tablet or feed premix.. It would be obvious to vary the form of the formulations to optimize the effect desired, depending upon the particular species and application method of interest, reduction of toxicity, cost minimization, enhanced, and prolonged, or synergistic effects. Applicant has not provided any objective evidence of nonobvious or unexpected results that the administration of the particular ingredients' combination or formulation provides any greater or different level of prior art expectation as claimed, and the use of ingredient for the functionality for which they are known to be used is not basis for patentability.

The premix is shown by the prior art in terms of active compounds similar to fipronil derivatives having a thioamide group at the 3 position of the pyrazole ring; other substitutions of the fipronil structure are permitted. The specific fipronil or aryl pyrazole compounds of the premix would not be critical to the function as a premix. One in the art would expect to be able to make a premix of any of the phenylpyrazole derivatives of fipronil, utilizing known excipients as described in the cited references.

Applicant argues the claimed thioamide derivatives are not shown. However, Claim 39 shows one of many intended thioamide derivatives of fipronil of Claim 37, and this is not a novel compound, as Alig had it. It is an effective pesticide suitable for oral, topical and agricultural uses, with or without additional pesticides. As such, there is every expectation that any such compound would be able to be prepared as a premix, using the recited excipients. The arguments for efficacy and unpredictability, with all due respect, are seen to fail. What is claimed is a premix, not a method of control of anything.

Double Patenting

Claim 26, 29, 33, 37 & 39 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 4, 5, 8-10, 13, 15-21, 23-29, 33 of copending Application No. 11/580,731. Although the conflicting claims are not identical, they are not patentably distinct from each other because the 11/580,731 would anticipate the instant claimed invention. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

At this time, neither case has been allowed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619.

The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT A. WAX can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NEIL LEVY/
Primary Examiner, Art Unit 1615
4/30/2010